

# REOX



ArtOral  
Klaus Mütterthies REOX

Notified Body: "KIWA CERMET N° 0476"  
Medical Device class IIa  
Directive 2007/47/CEE  
D.L.vo n. 46 del 24/02/97

## SAFETY DATA SHEET

# ArtOral KM System e ArtOral ZR System

Rev. 01 del 01/12/2019

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

### 1.1 Identification of the product

Reox Name: ArtOral KM System e ArtOral ZR System

Use: Art Oral KM e Art Oral ZR Dental ceramic powder; opaque powder; stain; glaze;

- Medical Device Class IIa - Directive 93/42 / EEC

### 1.2 Application of the product

Intermediate product for dental ceramic restoration

Alkali-alumo-silicate-matrix with more oxidized, homogeneous bond components as well as oxidized bond color pigments, opacifying agent and fluorescence material.

### 1.3 Company

REOX SRL Unipersonale, via delle Industrie, 29/h

30020 Marcon (ve) TEL. 041 5952896

E-mail: [info@reox.it](mailto:info@reox.it) sito internet: [www.reox.it](http://www.reox.it)

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

The substance is not classified according to the CLP regulation 1272/2008 CPL

Information concerning particular hazards for human and environment: Not applicable.

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008	Void
Hazard pictograms	Void
Signal word	Void
Hazard statements	Void

### 2.3 Other hazards

Dust generation

Particular danger of slipping for leaked product.

Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable.

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**3. COMPOSITION/ INFORMATION ON INGREDIENTS**

## 3.1 Chemical characterization: Substances

CAS-number / description: 85422-94-2 / ceramic materials

## 3.2 Hazardous components:

Additional information: For the wording of the listed risk phrases, see section 16.

**4. FIRST AID MEASURES**

## 4.1 Description of the first aid actions

Cause	Removal
Inhalation	Move person into fresh air. If not breathing give artificial respiration Consult a physician.
Skin contact	Wash off with soap and plenty of water.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Swallow	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

## 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

## 4.3 Indication of any immediate medical attention and special treatment needed

Consult a physician. Show this safety data sheet to the doctor in attendance.

**5. FIRE-FIGHTING MEASURES**

Indication	Remarks
Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	Unknown
Special risks	Unknown - The product itself does not burn.
Special protective equipment	Wear self contained breathing apparatus for fire fighting if necessary.

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**6. ACCIDENTAL RELEASE MEASURES****6.1 Precautionary measures personal**

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

**6.2 Environmental protection measures**

Do not let product enter drains. Gather mechanically the material and store in a container.

**6.3 Procedures for cleaning**

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

**7. HANDLING AND STORAGE****7.1 Handling**

No special measures required. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

**7.2 Storage**

Recommended storage temperature: +12°C to +38°C. Keep container tightly closed in a dry and well-ventilated place.

**7.3 Special Application (-s)**

Use only for dental technician/ dentist or trained personal. See instructions for use!

**8. EXPOSURE CONTROL AND PERSONAL PROTECTION****8.1 Limited exposure values**

General limitation (TRGS 900):

Exposition: alveolar Exposure 3mg/m<sup>3</sup> (< 1-4µm)

Exposition: inhaled Exposure 10mg/m<sup>3</sup> (> 4µm)

**8.2. Limitation and Control of Exposure for the Working Place**

Protection	Description
Respiratory protection	Indossare una maschera di protezione delle vie respiratorie durante il lavoro (Filtro P2)
Hand protection	Non applicabile
Eye protection	Indossare occhiali protettivi per gli occhi durante il lavoro
Body protection	Non sono necessarie misure di protezione

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Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday

**9. PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1 General information

	Description
Color	Different shades for the different types of tooth color
Physical State/Appearance	solid powder
Odour	odourless

## 9.2 Important information on health and environment protection and safety

	Description
pH Value	Not applicable
boiling point	Not applicable
Flash point	Not applicable
Flammability	Not applicable
Melting point	approx. 650°C - 1000°C
Risk for explosion	Explosion limits not applicable
Fire supporting features	Not applicable
Relative density	approx. 2,3 g/cm <sup>3</sup> – 3.0 g/cm <sup>3</sup>
Solubility	Insoluble in water

**10. STABILITY AND REACTIVITY**

## 10.1 Reactivity

No further relevant information available.

## 10.2 Chemical stability

Stable under normal handling and storage conditions.  
 Thermal decomposition / conditions to be avoided:

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No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions  
No dangerous reactions known.

10.4 Conditions to avoid  
No further relevant information available.

10.5 Incompatible materials:  
No further relevant information available.

10.6 Hazardous decomposition products:  
None under normal conditions of storage and use.

**11. TOXICOLOGICAL INFORMATION**

11.1 Information on toxicological effects

Acute toxicity

No harmful actions have been observed with the use of this product

Irritation and corrosion

No harmful actions have been observed with the use of this product

Sensitisation

No harmful actions have been observed with the use of this product

Chronic exposure

No harmful actions have been observed with the use of this product

Signs and Symptoms of Exposure

No harmful actions have been observed with the use of this product

11.2 Potential Health Effects

Inhalation

Harmful if inhaled. May cause respiratory tract irritation.

Skin

May be harmful if absorbed through skin. May cause skin irritation

Eyes

May cause eye irritation

Ingestion

May be harmful if swallowed.

*Can damage the lungs*

11.3 Additional toxicological information:

The substance is not subject to classification according to the latest version of the EU lists

**12. ECOLOGICAL INFORMATION**

12.1 Toxicity

Aquatic toxicity:

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

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12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

**13. DISPOSAL CONSIDERATIONS**

13.1 Waste treatment methods

Recommendation: Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

13.2 Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

**14. TRANSPORT INFORMATION**

Indication	Description
UN-Number ADR, ADN, IMDG, IATA	Void
UN proper shipping name ADR, ADN, IMDG, IATA	Void
Transport hazard class(es) ADR, ADN, IMDG, IATA	Not applicable.
Packing group ADR, IMDG, IATA	Not applicable.
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

**15. REGULATIONS**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
 According to CE guidelines, the product is not subject to the obligation of marking.  
 The product is a medical device according to the Directive 93/42/EEC, classe II

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**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**16. OTHER INFORMATION**

The information contained herein is based on the present state of knowledge. The Safety Data Sheet describes the product with regard to the appropriate safety precautions. The instruction It does not represent a guarantee of the properties of the product.

**Abbreviations and acronyms**

**RID:** Reglement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail);

**ICAO:** International Civil Aviation Organization;

**ADR:** Accord europeen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road);

**IMDG:** International Maritime Code for Dangerous Goods;

**IATA:** International Air Transport Association;

**EINECS:** European Inventory of Existing Commercial Chemical Substances;

**CAS:** Chemical Abstracts Service (division of the American Chemical Society).

**Manufacturer and Distributor****REOX SRL Unipersonale**

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Rev.	Del	Reason for revision
01	01/12/2019	Updated document